

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Appl. Serial No.:** 10/623,189

**Patent No.:** 7,183,254 B2

**Inventors:** Alexander De Paoli, et al.

**Filed:** July 18, 2003

**Title:** USE OF LEPTIN FOR TREATING HUMAN  
LIPOATROPHY AND METHOD OF DETERMINING  
PREDISPOSITION TO SAID TREATMENT

**Confirmation No.:** 3581

**TC/A.U.:** 1646

**Examiner:** O'Hara, Eileen B.

**Request for Certificate of Correction Under 37 C.F.R. § 1.323**

**Attention: Certificate of Correction Branch**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.323, Patentee hereby requests that a Certificate of Correction be issued to correct errors in the claims for the above-identified patent. Patentee notes that the correction requested herein is necessitated as a result of Applicant error. Specifically, two co-assignees or record were inadvertently, and without deceptive intent, omitted from the issue fee transmittal form that was completed and filed in order to effect payment of the issue and issuance of the above identified case.

In support of this Request for Certificate of Correction Under 37 C.F.R. § 1.323, Applicant submits copies of the following Documents as evidence:

1. Patent Assignment Abstract of Title printed from USPTO website March 12, 2008, indicating that the following entities have been recorded co-assignees of the above-identified issued US Patent, and that each executed assignment has been

---

CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. 1.10 OR  
TRANSMISSION UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being electronically filed with the USPTO via the USPTO EFS-Web electronic filing system on the date shown below.

March 12, 2008  
Date of Deposit

/Michael D. Ruse, Jr.  
Signature of Person Mailing Paper

Michael D. Ruse, Jr.  
Name of Person Mailing Paper

accorded a valid reel and frame number: The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, reel and frame number 017036/0674; Board of Regents, The University of Texas System, reel and frame number 017036/0693; and Amgen Inc., reel and frame number 017036/00640;

2. Copy of Issue Fee Transmittal (PTOL-85) mailed November 29, 2006, indicating only Amgen Inc. as assignee; and
3. Copy of cover page of U.S. Patent No. 7,208,577, indicating only Amgen, Inc. as assignee in Item (73).

Therefore, because, ownership of the above-identified issued US Patent has been properly recorded by the United States Patent and Trademark Office as evidenced by the valid reel and frame numbers which correspond to fully executed assignments to each respective assignee, the omission of The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, and the Board of Regents, The University of Texas System from item (73) on the cover page of the subject Patent is in error and should be corrected.

Therefore, Applicant respectfully requests the issuance of the Certificate of Correction as submitted herewith. Because the omission of The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, and the Board of Regents, The University of Texas System from item (73) resulted from Applicant's inadvertent failure to indicate these entities as co-assignees on the Issue Fee Transmittal form that was filed in the above-identified case, the error constitutes an error on the part of Applicant. Accordingly, Applicant herewith provides the associated fee as required under 37 C.F.R. § 1.20(a).

Additionally, if any other fees should become due in connection with this submission the commissioner is hereby authorized to charge any fee deficiency, and/or credit any overpayment, to Deposit Account No. 010535, referencing docket number 1311US-CON.

Respectfully submitted,  
AMYLIN PHARMACEUTICALS, INC.

Date: March 12, 2008

/Michael D. Ruse, Jr./  
Michael D. Ruse, Jr.  
Registration No. 55,900

**AMYLIN PHARMACEUTICALS, INC.**  
9360 Towne Centre Drive  
San Diego, CA 92121  
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Facsimile: (858) 552-1936

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,183,254 B2

APPLICATION NO.: 10/623,189

ISSUE DATE : February 27, 2007

INVENTOR(S) : Alexander M. DePaoli; Simeon I. TAYLOR; Elif A. ORAL; Abhimanyu GARG

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At Item (73) Assignee:, please insert the following:

The Government of the United States of America, as represented by the Secretary, Department of Health and Human Services, Rockville, MD (US);

Board of Regents, The University of Texas System, Austin, TX (US)

MAILING ADDRESS OF SENDER (Please do not use customer number below): Amylin Pharmaceuticals, Inc.  
9360 Towne Centre Drive  
San Diego, CA 92121

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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## Patent Assignment Abstract of Title

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## Total Assignments: 4

Patent #: 7183254

Issue Dt: 02/27/2007

Application #: 10623189

Filing Dt: 07/18/2003

Publication #: 20050020496

Pub Dt: 01/27/2005

Inventors: Alexander M. DePaoli, Elif A. Oral, Simeon I. Taylor, Abhimanyu Garg

Title: USE OF LEPTIN FOR TREATING HUMAN LIPOATROPHY AND METHOD OF DETERMINING PREDISPOSITION TO SAID TREATMENT

## Assignment: 1

Reel/Frame: 017036/0674

Recorded: 01/19/2006

Pages: 6

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: TAYLOR, SIMEON I.

Exec Dt: 07/11/2004

ORAL, ELIF A.

Exec Dt: 07/15/2004

Assignee: THE GOVERNMENT OF THE UNITED STATES OF AMERICA, AS REPRESENTED BY THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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SUITE 325

ROCKVILLE, MARYLAND 20852-3804

Correspondent: LAUREN SLIGER

P.O. BOX 1208

SEATTLE, WA 98111-1208

## Assignment: 2

Reel/Frame: 017036/0693

Recorded: 01/19/2006

Pages: 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: GARG, ABHIMANYU

Exec Dt: 09/20/2004

Assignee: BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM

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AUSTIN, TEXAS 78701

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SEATTLE, WA 98111-1208

## Assignment: 3

Reel/Frame: 016925/0387

Recorded: 10/21/2005

Pages: 9

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: DEPAOLI, ALEX M.

Exec Dt: 04/26/2005

TAYLOR, SIMEON I.

Exec Dt: 07/11/2004

ORAL, ELIF A.

Exec Dt: 07/15/2004

GARG, ABHIMANYU

Exec Dt: 09/20/2004

Assignees: AMGEN INC.

ONE AMGEN CENTER DRIVE

LAW DEPARTMENT

THOUSAND OAKS, CALIFORNIA 91320-1799

GOVERNMENT OF THE UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE  
BOX OTT

NATIONAL INSTITUTES OF HEALTH, OFFICE OF TECHNOLOGY TRANSFER  
BETHESDA, MARYLAND 20892-9902  
BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM  
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AUSTIN, TEXAS 78701

**Correspondent:** PERKINS COIE LLP  
POST OFFICE BOX 1208  
SEATTLE, WA 98111-1208

**Assignment: 4**

**Reel/Frame:** 017036/0640

**Recorded:** 01/19/2006

**Pages:** 5

**Conveyance:** CORRECTIVE ASSIGNMENT TO REMOVE THREE CONVEYING PARTY NAMES, AND TO REMOVE TWO RECEIVING PARTY NAMES AND ADDRESSES AND TO CORRECT THE UNDERLYING ASSIGNMENT DOCUMENT PREVIOUSLY RECORDED AT REEL 016925, FRAME 0387.

**Assignor:** DEPAOLI, ALEX M.

**Exec Dt:** 04/26/2005

**Assignee:** AMGEN INC.

ONE AMGEN CENTER DRIVE  
THOUSAND OAKS, CALIFORNIA 91320-1799

**Correspondent:** LAUREN SLIGER  
P.O. BOX 1208  
SEATTLE, WA 98111-1208

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Web interface last modified: April 20, 2007 v.2.0.1

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# PART B - FEE(S) TRANSMITTAL

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 Amylin Pharmaceuticals, Inc.  
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Rachel Potash (Depositor's name)  
 Rachel Potash (Signature)  
 November 29, 2006 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,189	07/18/2003	Alexander M. DePaoli	54113.8005.US02	3581

TITLE OF INVENTION: USE OF LEPTIN FOR TREATING HUMAN LIPOATROPHY AND METHOD OF DETERMINING PREDISPOSITION TO SAID TREATMENT

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$0	\$1700	11/29/2006

EXAMINER	ART UNIT	CLASS-SUBCLASS
O'HARA, EILEEN B	1646	514-01/2000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

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 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

Amylin  
 Pharmaceuticals, Inc.  
 3

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PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

Amgen, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Thousand Oaks, CA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

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☒ Publication Fee (No small entity discount permitted)  
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5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature Michael D. Ruse, Jr.  
 Typed or printed name Michael D. Ruse, Jr.

Date November 29, 2006  
 Registration No. 55,900

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US007183254B2

(12) **United States Patent**  
**DePaoli et al.**

(10) **Patent No.:** **US 7,183,254 B2**  
(45) **Date of Patent:** **Feb. 27, 2007**

(54) **USE OF LEPTIN FOR TREATING HUMAN LIPOATROPHY AND METHOD OF DETERMINING PREDISPOSITION TO SAID TREATMENT**

(75) Inventors: **Alexander M. DePaoli**, Santa Barbara, CA (US); **Simeon I. Taylor**, Skillman, NJ (US); **Elif A. Oral**, Ann Arbor, MI (US); **Abhimanyu Garg**, Dallas, TX (US)

(73) Assignee: **Amgen, Inc.**, Thousand Oaks, CA (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 284 days.

(21) Appl. No.: **10/623,189**

(22) Filed: **Jul. 18, 2003**

(65) **Prior Publication Data**

US 2005/0020496 A1 Jan. 27, 2005

#### **Related U.S. Application Data**

(63) Continuation of application No. 10/279,129, filed on Oct. 22, 2002, now abandoned.

(60) Provisional application No. 60/336,394, filed on Oct. 22, 2001.

(51) **Int. Cl.**

**A61K 38/00** (2006.01)

**A61K 38/16** (2006.01)

**C07K 14/00** (2006.01)

(52) **U.S. Cl.** ..... **514/12**; 424/184.1; 424/198.1; 530/350

(58) **Field of Classification Search** ..... None  
See application file for complete search history.

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WO	WO 96/23514	8/1996
WO	WO 96/23515	8/1996
WO	WO 96/23516	8/1996
WO	WO 96/23517	8/1996
WO	WO 96/23518	8/1996
WO	WO 96/23519	8/1996
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(Continued)

*Primary Examiner*—Eileen B. O'Hara

(74) *Attorney, Agent, or Firm*—Amylin Pharmaceuticals, Inc.

(57) **ABSTRACT**

Leptin, leptin analogs, and leptin derivatives are used to treat patients with lipoatrophy. Leptin is effective against conditions of lipoatrophy for both genetic and acquired forms of the disease. A therapeutically effective amount of leptin can be administered in a variety of ways, including subcutaneously and using gene therapy methods. Methods of the present invention contemplate administration of leptin, leptin analogs, and leptin derivatives to patients having a leptin level of approximately 4 ng/ml or less before treatment.

**30 Claims, 6 Drawing Sheets**